IV. REMARKS

The applicant thanks the examiner for noticing the spelling error in claim 132. This has been corrected as well as the occurrence in paragraph 33 of the specification.

The test modality concerns raised relative to the enablement and written description concerns of the action have been resolved through amendment as proposed as indicated to resolve the concern in the personal interview. Although the applicant respectfully disagrees with the stated concerns these concerns have been resolved here for claims 18-20, 46, 54-69, 73-82, 105-106, 110-113, and 132-136 by inserting into base claim 18 the suggested three test modalities recognized in the action as being supported by the specification by way of the prior art. Note this is done without prejudice as the applicant respectfully disagrees and reserves right to present additional scope at a later date likely in one or more subsequent continuing application(s). Further, as to these claims as well as claims 43-45, it is respectfully explained that, the possession question raised – if it is eventually determined to be valid – is not applicable in this case because of the nature of the claim(s) and the fact that the precise claims at issue are not late additions but rather have been present in the priority case. Here claims 43-45 have been present in the application since the priority PCT case. Indeed, the original language of these exact claims is identically present as claims 43-45 of the PCT priority case (they even have the same numbers in the PCT publication). Of course, this graphically shows that the invention as set forth in these particular claims was clearly possessed by the applicant.

In this regard, the Supreme Court has held that the measure of the sufficiency of a written description for a claimed invention is whether the description enables a skilled artisan to make and use the invention. *See, The Telephone Cases*, 126 U.S. 1 (1888). Second, the Federal Circuit's commentary currently in *Ariad v. Eli Lilly* currently under en banc review relative to detailed biochemical claims does not suggest that the claims at issue here need a particularly detailed description to show possession. *See generally, Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1372 (Fed. Cir. 2009)(claims need not recite the claimed invention *in haec verba*, they just need to establish that the applicant was in possession of the claimed invention, including all of the elements and limitations). That this level of possession exists in the relevant claims is evident from the simple fact that claims 43-45 have been present in the application since the priority PCT case. Indeed, the priority case shows possession. Furthermore, the claims at issue are not of a chemical groundbreaking nature where classes of biochemicals not originally included need to be understood.

There is not even a paucity of prior art relative to the claimed subject matter. Numerous articles beyond the three that happened to be identified in the action are readily available and both these self-proving documents and affidavit evidence can be supplied, if necessary, to show that in advance of the relevant date those of ordinary skill in the art understood a number of tests were available to indicate a variety of deficiencies. This is especially true for tests that have lower correlation where even question-response types of tests can be accomplished, indicated, or explained at even a diagnosis level.

Most importantly, even with the current state of the *Ariad* case (before the en banc result is indicated), the Federal Circuit has stated that the potential the written description requirement is "a fact-based inquiry that will depend on the nature of the claimed invention and the knowledge of one skilled in the art" and that such factors include the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and the predictability of the aspect at issue. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1372-73 (Fed. Cir. 2009). In this case, the claimed invention is not in a new or

unpredictable field where the existing knowledge and prior art was scant. The claims do not invent the deficiency tests, they only set forth applying them in a unique manner. This does not require a research plan, it only calls for some diligence of inquiry into existing known techniques. Thus the claimed invention meets a proposed written description requirement if it is eventually determined to exist at the proposed level. As to such possible precedent, it merits mentioning that the applicant reserves rights to raise further issues from the ultimate determination as it issued in the pending en banc Federal Circuit hearing on the *Ariad Pharms., Inc. v. Eli Lilly & Co.* case. This should be understood as also resolving all concerns as to claims with alternative tests and the like as raised in the action.

Finally, in the claim listing it should be noted that claim 136 is included. In the action, the grounds of rejection for claim 136, have not been precisely indicated. To move the case forward nonetheless, the applicant has assumed the ground for this claim exists merely via dependency and this particular claim number was simply overlooked in the listing of dependency-based claims on page 15 of the action.

As to claims 10-17 and 18-20 and 43-46, 54-68, 73-77, and 79-82 the potential confusion over the term "separate" has been resolved as agreed in the interview by specifying in claims 10, 18, and 43 that the test strips test for a deficiency. As discussed and accepted in the interview, this is believed to resolve the possible uncertainty expressed and no other comment is necessary. To address the concerns raised as to claims 69 and 78, the language of these claims has been similarly modified as suggested to clarify that which is intended.

Regarding the use of the language of claim 105, it is respectfully submitted that the words used are adequately understood by a person of ordinary skill in the art and need no further delineation. Such understandings are explained in the specification (see PCT publication page 15) stating:

> "[Tests] can vary and may also present a test which is either directly or even indirectly relevant to some aspect of use of the particular substance involved. In one embodiment the test may present simply a qualitative test modality. It may also present a semi-quantitative test modality or may even be fully configured to provide a quantitative test modality. In instances where the absolute value is relevant, an absolute value test or absolute value test modality may be used similarly in instances where only a relative value is meaningful, a relative value test modality may be used. This may even be combined with some type of personal baseline test result so that constant comparisons can be made to show progress. Even a rate of change test modality may be used. Similarly, other substances and other tests may be presented even beyond a supplement context ranging from sexually transmitted disease tests to multiple regimen tests, that is tests where more than one result is combined to achieve more accurate results."

Furthermore the specification (see PCT publication page 20) incorporates by reference precise definitions stating that definitions "contained in the Random House Webster's Unabridged Dictionary, second edition are hereby incorporated by reference." As a person of ordinary skill in the art understands, the term "quantitative" is thus a known word defined in the incorporated reference as "1. that is or may be estimated by quantity. 2. of or pertaining to the describing or measuring of quantity." Similarly the term "qualitative" is defined in the incorporated reference as "pertaining to or concerned with quality or qualities" with "quality" including, *inter alia,* the definition "1. an essential or distinctive characteristic, property, or attribute; 2. character or nature, as belonging to or distinguishing a thing." And finally the qualifier "semi" is defined in the incorporated reference as:

> "a combining form borrowed from Latin, meaning 'half,' freely prefixed to English words of any origin, now sometimes with the senses 'partially,' 'incompletely,' 'somewhat'."

Other terms, of course, have similar incorporated definitions. Thus, once fully understood as various portion of the specification detail, the meanings of the terms in claim 105 are not vague. A person of ordinary skill in the art would well understand such meanings, and such meanings are even explicitly incorporated by reference into the specification, thus the requirements of section 112 are met. Of course, these incorporated definitions could be inserted in the specification, however, given the general understandings of those skilled in the art, this is not believed necessary at this point in time.

Regarding the use of the language "highly correlates" in claim 106, it is respectfully submitted that such a term is adequately understood by a person of ordinary skill in the art and needs no further delineation. Such understandings are even quantitatively stated in the specification in paragraph 21 stating:

> "This high correlation may be something that is statistically proven with perhaps varying degrees of uncertainty of result. Thus the statistical test may be one with a statistical P factor being anywhere from about 0.05 to 0.10 to 0.15."

Probability or P factors of at most or less than about 0.05, at most or less than about 0.10, or at most or less than about 0.15 are all ways to provide a test that highly correlates with a deficiency, desire, need, or the like. Of course, these alternatives for P factor numbers could be inserted in the claim to even further narrow its interpretation, however, given the general understandings of those skilled in the art, this is not believed necessary at this point in time.

Similarly, the converse now appearing as language in the specification and claims 110, 111, and 112 (and 113 by dependency) where the test modality is one that has a "lower correlation" with the use of a substance is also adequately understood by a person of ordinary skill in the art and needs no further delineation to meet the requirements of the enablement or written description. In addressing earlier concerns of the patent office, this language was used to highlight and detail an aspect set forth in paragraph 21 of the original specification, namely, using a test modality that is "indirectly indicative" of the particular deficiency, desire, need, or the like. To address the action's concerns, it is affirmatively stated that the earlier insertion of the "lower correlation" language is intended to merely provide more elegant language that details the language and idea present in the initial application, namely, the initially specified aspect of an indirectly indicative test. In fact, paragraph 21 of the specification provides a standard for ascertaining the requisite degree of correlation and it can be understood as informing a probability or P factor that is the other side of the quantitative spectrum, namely, a P factor of at least or greater than about 0.05, at least or greater than about 0.10, or at least or greater than about 0.15. Each of these is a way to provide a test that is indirectly indicative or ends up having a lower correlation with a deficiency, desire, need, or the like. In fact, the two ends of the spectrum can be used as a guide where a test having a P factor (to the extent known or ascertainable at any point in time) of at most or less than about 0.05 is a "highly correlated" test and conversely, a test having an unknown probability, is merely a diagnostic, or has a P-factor (to the extent known or ascertainable to some degree) of at least or greater than about 0.15 (or other option specified) is a "lower correlation" test. Of course, the specification language of selecting a test modality that is indirectly indicative of the use of a particular substance could be used with the above understanding, or the alternative P factor numbers of the specification could be inserted in these claims to even further narrow their interpretations, however, given the

general understandings of those skilled in the art, this is also not believed necessary at this point in time. Such claim language is respectfully explained as clearly meeting both the enablement and written description requirements. A person of ordinary skill in the art would understand the specification and would not consider such terms as vague. Furthermore, unquestionably such language meets the present guidance in *Ariad*, and the aspect of lower correlation as defined above was clearly in possession of the applicant. As *Ariad* stated, such language need not be recited *in haec verba*, there just has to be enough to show possession. This is evident because every one of these above aspects was present in the application since the priority PCT case. As the action tacitly admits, only the idea of "lower correlation" need be possessed. There can be no question that the "lower correlation" language need not be present *in haec verba*. In fact, even under the most rigorous standard (if it were ultimately adopted) the idea of a lower correlation was clearly possessed by the applicant as explained above.

Finally, the section 103 concerns are believed resolved by the above amendment and the understandings discussed in the interview as set forth below. To reiterate, it is understood (as Supervisor Haghighatian highlighted in the interview) that the concern is not a matter of showing operation of the invention, but rather one of obviousness in view of the art cited. In this regard (as tentatively accepted in the interview subject to final consideration), it is respectfully reiterated in summary fashion that the cited references to not, in fact, make the claimed invention obvious. The prior explanations are also incorporated here; however, the following reiterates some of the issues explained in the interview with respect to independent claims 10, 18, and 43. Where the action expressed concerns as to Azari in view of Cherukuri as evidenced by Gurol for claims 10, 18, and 43, it should be understood that the cited references to not evidence the elements now set forth in the amended claims. First, the action does not identify, and the references to not contain any of: the amended element of a test that tests for a calcium deficiency in a user as set forth in claim 10; the amended elements of either i) containing a separate amount of a calcium supplement substance, insulin substance, or prescribed medication substance by a distribution container, ii) selecting a separate test modality that tests for a deficiency of one of said substances in a user, or iii) establishing a procedure for use of said separate test modality, each as set forth in claim 18; or the amended elements of either i) a physically separate amount of a separately ingestible supplement, ii) a distribution container within which said physically separate amount of said separately ingestible supplement is contained, or iii) a compactly assembled plurality of test strips that test for a deficiency of said supplement in a user attached to the distribution container, each as set forth in claim 43. Of course, even if the action were to address these elements, as recognized in the action, Azari does not teach calcium as set forth in amended claims 10 and 18. Further, even its saliva-inducing purpose for chewing gum does not involve any item supplied with a separate supplement, or even a medication as included in claims 10, 18, and/or 43. Similarly, Cherukuri also has no separately supplied supplement or medication and thus thus does not address the missing elements and cannot make the claimed invention obvious. Finally, Gurol is supplied only to state that an antacid neutralizes an acid. It neither adds the missing elements nor makes the items obvious. Thus, as discussed in the interview, the references do not and cannot make claims 10, 18, or 43 obvious. Even if each of the teachings supplied are combined, the combined references to add the missing elements, and none of the references test for a deficiency or are supplied with a separate supplement or medication of the type mentioned. Dependencies are likewise not obvious.

Similarly, even where the action expressed concerns citing only Beckers as to claims 18 and 43, it should be understood that the Beckers reference does not evidence the elements now

set forth in the amended claims. As admitted, Beckers is only a diabetes management system. It does not involve supplying an attached or assembled test item with a supplement or a medication. It merely is a test apart from the insulin which is done as a "follow up" (col.4, line 14). It, alone, cannot make the claimed invention obvious. Once more, the prior explanations are also incorporated, and once more the action does not identify, and this singular reference does not contain any of: the amended elements of either i) containing a separate amount of a calcium supplement substance, insulin substance, or prescribed medication substance by a distribution container, ii) selecting a separate test modality that tests for a deficiency of one of said substances in a user, or iii) establishing a procedure for use of said separate test modality, each as set forth in claim 18; or the amended elements of either i) a physically separate amount of a separately ingestible supplement, ii) a distribution container within which said physically separate amount of said separately ingestible supplement is contained, or iii) a compactly assembled plurality of test strips that test for a deficiency of said supplement in a user attached to the distribution container, each as set forth in claim 43. Thus, as discussed in the interview, this singular reference does not and cannot make claims 18 or 43 obvious. The singular reference cannot add the missing elements, and it does not involve supplying a separate supplement or medication in the manner mentioned. Again, the dependencies are likewise not obvious.

Finally as to the independent claims, where the action expressed concerns only citing Kaish for claims 18 and 43, it should be understood that the Kaish reference also does not evidence the elements now set forth in the amended claims. As admitted, Kaish is only a patient run test device for peak expiratory flow rate testing. As also admitted, this does not involve supplying an attached or assembled test item with a supplement or a medication. Like Beckers, it merely is a test apart from any other activity. As Kaish explains, this is merely a test after which one can take their prescribed medications if appropriate. (col.1, line 45). It, alone, cannot make the claimed invention obvious. Once more, the prior explanations are also incorporated, and once more the action does not identify, and this singular reference does not contain any of: the amended elements of either i) containing a separate amount of a calcium supplement substance, insulin substance, or prescribed medication substance by a distribution container, ii) selecting a separate test modality that tests for a deficiency of one of said substances in a user, or iii) establishing a procedure for use of said separate test modality, each as set forth in claim 18; or the amended elements of either i) a physically separate amount of a separately ingestible supplement, ii) a distribution container within which said physically separate amount of said separately ingestible supplement is contained, or iii) a compactly assembled plurality of test strips that test for a deficiency of said supplement in a user attached to the distribution container, each as set forth in claim 43. Thus, as discussed in the interview, this singular reference does not and cannot make claims 18 or 43 obvious. The singular reference cannot add the missing elements, and it does not involve supplying a separate supplement or medication in the manner mentioned. Again, dependencies are similarly not obvious.

V. Conclusion

In the September 3, 2009 non-final office action, the Office questioned concerns under 35 USC §§112 and 103 to certain claims. These were further clarified in the interview conducted October 13, 2009. In response, the Applicant submits this amendment, explanation and request for reconsideration to fully address the concerns as clarified. The Applicant believes all concerns have been addressed and that all claims remaining in the case – claims 10-20, 43-46,

54-69, 73-82, 105-106, 110-113, and 132-136 – are in condition for allowance. Reconsideration and allowance of these claims is respectfully requested at the Examiner's earliest convenience. Finally, should the Examiner have any remaining questions or disagree with any of Applicant's explanations, it is requested that the Examiner contact the undersigned by telephone in order schedule a personal interview and to expedite the processing of this application.

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Respectfully Submitted,
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